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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,315	MARTIN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19,21,22,24-26 and 28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 19, 21-22, 24-26 and 28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on June 17, 2004 and wherein claim 31 has been amended. Claims 1-16, 18, 20, 23, and 27 are cancelled previously.

Currently, claims 17, 19, 21-22, 24-26 and 28-40 are pending in this application.

Claims 17, 19, 21-22, 24-26 and 28-40 will be examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19, 21-22, 24-26 and 28-40 are rejected under 35 U.S.C. 112, first paragraph, for **scope** of enablement because the specification, while being enabling for treating, increasing or tightening the firmness of skin, i.e., preventing the loss of firmness or elasticity of skin, including preventing, retarding, arresting, or reversing the wrinkles in the skin (see page 3 lines 1-20 of the specification) disclosed in the specification employing a Hedychium extract herein, does not reasonably provide enablement for relaxing or decreasing the firmness of skin, for the same reasons of record stated in the Office Action dated January 13, 2004.

The skilled artisan would view that the recitation, "**regulating** the firmness, tone, or texture of skin of a subject or **regulating** wrinkles in skin of a subject",

encompassing both increasing and decreasing the firmness, tone, or texture of skin of a subject or both increasing and decreasing wrinkles in skin of a subject, in both directions.

The instant claims are drawn to the methods for regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to the methods for regulating, i.e., encompassing both increasing and decreasing the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject.

The state of the prior art: The skilled artisan would view that regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including increasing and decreasing the wrinkles in the skin, are highly unlikely.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that, regulating, encompassing both increasing and decreasing, the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject, is highly unpredictable since the skilled artisan would not understand how the same compound or agent could increase and decrease the firmness, tone, or texture of skin of a subject or wrinkles in skin of a subject.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to use the herein to regulate the firmness, or tone of skin of a subject herein, or how to prevent, retard, arrest, or reverse the wrinkles in the skin. Applicant's specification provides the experimental results merely showing *in vitro* effects of a hedychium extract (see page 11-15 of the specification).

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to achieve methods of regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including preventing,

retarding, arresting, or reversing the wrinkles in the skin, with no assurance of success.

Response to Argument

Applicant's arguments filed June 17, 2004 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement have been fully considered but are not deemed persuasive as further discussed below.

Applicant arguments that " The term 'regulating wrinkles in skin" is defined on page 3 of the specification to mean preventing, retarding, arresting, or reversing the process of wrinkle and fine line formation in skin." Thus, regulating the firmness or tone of skin of a subject or regulating wrinkles in skin" is not defined by the Applicants to encompass both increasing wrinkles in the skin as argued on page 3 of the specification" have been considered but not found convincing. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

In this case, as pointed out previously. "regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject", encompassing both increasing and decreasing the firmness, tone, or texture of skin of a subject or both increasing and decreasing wrinkles in skin of a subject,

in both directions. Moreover, as discussed in the Office Action July 28, 2003, the skilled artisan would view that regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including preventing, retarding, arresting, or reversing the wrinkles in the skin, are highly unlikely and highly unpredictable. Over the years many attempts at stopping the aging process have been recorded. The results of many methods of pharmacological treatments have been uniformly unreliable and unsatisfactory in regard to preventing, retarding, arresting, or reversing firmness, or tone of skin of a subject or regulate wrinkles in skin of a subject.

Further, in the instant case, **no** working examples are presented in the specification as filed showing how to use the herein to regulate the firmness, or tone of skin of a subject herein, or how to prevent, retard, arrest, or reverse the wrinkles in the skin.

Therefore, as indicated in the previous Office Action, the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement. Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19, 21-22, 24-26 and 28-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiseido Co. Ltd (JP 61291515), for the same reasons of record stated in the Office Action dated January 13, 2004.

Shiseido Co. Ltd discloses that a hedychium extract in an effective amount such as 0.5% or 0.15% by weight (see JP 61291515 Table 1 and 2 at page 65; Example 1-2 at page 66), within the instant claimed range, is useful in a cosmetic composition with a cosmetically-acceptable carrier for topical administration and a method of treating hot feeling after sunburn, rough skin, razor rash and inflammations. See in JP 61291515, the abstract, and examples at page 65-69. Shiseido's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Shiseido's method steps are same as the instant method steps by topically applying the same composition in the same amounts to the same patient population, because, one of ordinary skill in the art would clearly recognize that sunburn, rough skin, razor rash and inflammation are **liable** to damage or affect skin firmness, tone, or cause winkles. Therefore, the patient population in JP 61291515 is deemed to the same patient in need of regulating the firmness or tone or wrinkles in skin of a subject herein after sunburn, rough skin, razor rash and inflammations. See *Ex parte Novitski*, 26 USPQ 2d 1389.

See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Shiseido Co. Ltd anticipates the claimed invention.

Response to Argument

Applicant's arguments filed June 17, 2004 with respect to this rejection of made under 35 U.S.C. 102(b) of record in the previous Office Action January 13, 2004 have been fully considered but are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Again, Applicants assertion that "The '515 patent does not does not teach the topical application of a composition to the skin of said subject in need of regulating its firmness or tone or regulating its wrinkles" is not found convincing. As indicated above, sunburn, rough skin, razor rash and inflammation are **liable** to damage or affect skin firmness, tone, or cause winkles. Thus,, "said subject in need of such regulating" recited in the claims herein is reasonably interpreted to encompass those patients taught by '515 patent. See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881(Fed. Cir. 2001).

Therefore, the patient population in JP 61291515 is deemed to the same or included patient population in need of regulating the firmness or tone or wrinkles in skin of a subject herein after sunburn, rough skin, razor rash and inflammations. Hence, the certainty for the inherent treatment herein as one criteria for determining inherency is clearly seen here, not mere probability or possibilities. The skin of the patient suffering after sunburn, rough skin, razor rash and inflammation would be certainly in need of such treatment because of

affected or damaged skins as to the firmness, tone, or winkles of the skin in that patient.

Thus, as discussed in the previous Office Action, Shiseido's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Shiseido's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, Shiseido Co. Ltd anticipates the claimed invention.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
August 30, 2004

SHAOJIA ANNA JIANG
PATENT EXAMINER
9/7/04